IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re the application of:	David Keith JAMES et al.
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Group Art Unit:	3762
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Examiner:	LAVERT, Nicole

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/Patricia Romanelli/

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Title: FETAL SURVEILLANCE

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APPEAL BRIEF PURSUANT TO 37 C.F.R. §41.37

Dear Sir:

This brief is filed in furtherance of the Notice of Appeal, filed in this case on June 25, 2010, in which the Applicants appealed the fourth rejection of Claims 1-39 of the above-identified application.

I. REAL PARTY IN INTEREST

The real party in interest is Monica Healthcare Limited, assignee of the above-identified application and located at University Park, Nottingham, United Kingdom NG7 2RD.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences that will directly affect, be affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-39 are currently pending in this application. Claims 1-39 have been rejected at least twice. Claims 1-39 are being appealed.

IV. STATUS OF AMENDMENTS

Concurrent with Applicants' filing of the Notice of Appeal on June 25, 2010 and in response to the Examiner's 35 U.S.C. §112 indefiniteness rejection of Claims 1-39, Applicants submitted amendments to Claims 1 and 22. Claim 1 was amended to clearly recite structure, while Claim 22 was amended to clearly recite method steps. The amendments have been entered by the Examiner.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter relates to apparatus (Claim 1) and a method (Claim 22) for detecting both the spatial and temporal behavior of a fetus. The apparatus includes an input (31, Figure 8) for receiving ECG data from a set of electrodes (11-14, Figure 8) that are adapted to be attached to a maternal abdomen. See Specification at page 14, lines 5-7, 19, and 20. The apparatus also has a waveform pre-processor for identifying a succession of fetal ECG complex waveforms within the received data (40, Figure 8), page 14, lines 20-26, and a waveform processor (50, Figure 8) that determines the differences in the shapes of a succession of fetal ECG complex waveforms over time. See page 14, line 28 to page 15, line 5.

The waveform processor 50 has at least one of : (a) a comparator (51, Figure 8) that is used to match the ECG complex waveforms to one of a plurality of stored templates (specification, page 15, lines 17-25, 27-32); (b) a phase detector for detecting a change in the phase of one of the ECG complexes relative to an adjacent ECG complex (specification, page 13,

lines 6-14 and page 16, lines 20-29); and (c) an integrator that detects changes in the amount of positive and/or negative energy during the period of time (specification, page 13, lines 15-20 and page 17, lines 1-10).

The apparatus has an event logger (70, Figure 8) that determines a number of fetal body movements during a period of time. See page 16, lines 3-9 and page 16, lines 29-32. Using the components described above, the claimed invention allows the user to accurately determine and record the spatial and temporal behavior of a fetus. See page 1, lines 3-4.

The claimed method for monitoring the fetus's behavior comprises the step of obtaining the fetal ECG data over a period of time. See page 14, lines 10-22 and page 15, lines 19-22. A succession of fetal ECG complex waveforms is identified within the data, page 14, lines 23-26, and the differences in the shapes of the succession of fetal ECG complex waveforms are determined over time. See page 14, line 32 to page 15, line 5. More specifically, the differences are determined by one or more of the steps of (1) matching the ECG complex waveforms to a plurality of stored templates, page 15, line 17 to page 16, line 20, (2) detecting a change of phase of one ECG complex relative to an adjacent ECG complex, page 16, lines 20-29, and (3) detecting changes in the amount of positive and/or negative energy in the fetal ECG complex waveforms by integration (page 17, lines 1-10).

Finally, the method for monitoring the fetus's behavior includes the step of determining a number of fetal body movements during the period of time from the differences. See page 13, lines 15-20 and page 17, lines 1-10.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection presented for review are (1) whether Claims 1-39 are unpatentable under 35 U.S.C. 112, second paragraph, as being indefinite in light of Applicants'

Amendment after Notice of Appeal, submitted on June 25, 2010, (2) whether Claims 1-10, 18-29, 37, and 38 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent Publication No. 2001/0014776 to Oriol et al. (Oriol '776) in view of U.S. Patent No. 4,211,237 to Nagel (Nagel), (3) whether Claims 12-14 and 31-33 are unpatentable under 35 U.S.C. 103(a) over Oriol '776 in view of Nagel and further in view of U.S. Patent No. 5,088,498 to Beach et al. (Beach), and (4) whether Claims 15-17, 20, 34-36, and 39 are unpatentable under 35 U.S.C. 103(a) as being obvious over Oriol '776 in view of Nagel and further in view of U.S. Patent No. 5,596,993 to Oriol et al. (Oriol '993).

VII. ARGUMENT

A. Rejection of Claims 1-39 under 35 U.S.C. §112, second paragraph

The Examiner rejected Claims 1-39 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated that Claims 1 and 22 are unclear whether the claim limitations "...by use of..." and "...by at least one technique..." are active method step recitations or structural recitations.

Concurrently with filing of the Notice of Appeal, Applicants have amended apparatus Claim 1 to more clearly define the invention by removing the listing of the techniques and, instead, recite the structure of a comparator, a phase detector, or an integrator. Applicants have also more clearly defined method Claim 22 by reciting the active method steps of matching the ECG complex waveforms, detecting a change in phase, and detecting a change in energy by integration. Support for these amendments can be found in the specification at page 12, line 25 to page 13, line 20, and page 16, line 17 to page 17, line 4. Apparatus Claim 1 now clearly sets out limitations of structure, while method Claim 22 now clearly sets forth steps in performing a method.

B. Rejection under 35 U.S.C. §103(a) over Oriol '776 in view of Nagel

The Examiner stated that Oriol '776 teaches a waveform processor for determining differences in the shapes of a succession of fetal ECG complexes, the processor including at least one of a comparator, a phase detector, or an integrator. But in fact, neither Oriol '776 nor Nagel teaches or make obvious the claimed invention.

Claims 1-3, 5, 6, 8, 10, 18-23, 25, 26, 29, 37, 38

With regard to Claim 1, while Oriol '776 teaches using a processor, or an "expert subsystem" having a "neural network," see Oriol '776 paragraph [0104] and Fig. 12, the processor of Oriol '776 does not determine the *differences* in the shapes of a succession of fetal ECG waveforms *over time*, as is required by Claim 1.

As used in the specification, an "ECG complex waveform" refers to the shape and form of the ECG signal. Applicants' specification states on page 14, line 29 to page 15, line 5 that the processor is a module that analyzes the fetal ECG data to locate specific features. Preferably, the identified features correspond to the waveform complexes (the shape and the form of the ECG data) that are illustrated in Figure 5 of the Applicants' drawings. The processor also identifies differences between the identified waveform complexes, page 14, line 32 to page 15, line 5.

The processor, or the "feature extraction system," of Oriol '776 does not do this. Paragraphs [0103]-[0129] describe both the overall purpose and the specific components of the feature extraction system. As described in paragraph [0106], the system of Oriol '776 breaks down the task of determining fetal health into different tasks: determining the behavioral state of the fetus, paragraphs [0108-0109], classifying the fetal heart rate deceleration pattern, paragraph [0110], classifying the fetal heart rate acceleration pattern, paragraph [0111], and classifying the contraction pattern, paragraph [0112]. The outputs are then fed into an algorithm, which sorts

the outputs and directs the output to a specific classifier based on the particular combination of outputs, paragraph [119]. This information is then forwarded to another algorithm which organizes and formats the information, paragraph [0129]. At no point does the processor of Oriol '776 determine the *difference* in the shape of one fetal ECG waveform when compared to a second fetal ECG waveform.

The Examiner also asserts (Examiners Action of January 25, 2010, page 3, lines 9-13) that Oriol '776 determines these differences in shape with at least one of a comparator that matches the waveforms to a plurality of stored templates, a phase detector that detects a change in the phase of one waveform relative to an adjacent waveform, and an integrator that detects changes in the amount of energy in the fetal ECG complex. In support of her assertion, the Examiner cites Oriol '776 paragraph [0131] and notes that she is interpreting the trend variables disclosed in paragraph [0131] as the technique or means that is being used to match the waveforms to the templates.

With regard to the Examiner's interpretation of trending variables as the means to match ECG data to a template, that same paragraph begins with a discussion of a clinician's need to review the data, implying that it is the *clinician*, not the processor, that is analyzing the ECG waveforms. This is exactly the opposite from the claimed invention in which it is the *processor* that identifies the waveform.

Further, paragraph [0131] does not teach using a template. Paragraph [0131] does mention a "specific pattern," but this does not refer to a template that has been stored in a memory. Instead, this sentence states only that the prior art describes what variables are necessary to analyze the pattern of *any particular ECG*. Stated differently, the "specific pattern" refers to the individual ECG pattern associated with the patient, not a stored template.

Paragraph [0131] of Oriol '776 does not disclose a phase detector, an integrator, or a comparator which compares the ECG shape and form (waveform) against a stored pattern. As described briefly above, paragraph [0131] discusses that the literature has established the important variables to be monitored and that the system of Oriol '776 provides plots of these important variables (lines 13-15). At no place in paragraph [0131], or in the entire Oriol '776 specification, can the Applicants find a comparator for matching the waveforms to a plurality of stored templates, a phase detector for detecting a change in the phase of one waveform relative to an adjacent waveform, or an integrator for detecting changes in the amount of energy in the fetal ECG complex. Nagel neither discloses nor suggests this structure, either. The failure of either reference to disclose or suggest this structure shows that Claims 1-10 and 18-21 are patentable over Oriol '776 and Nagel.

With regard to Claim 22, the combination of Oriol '776 and Nagel do not determine the *differences* in the shapes of a succession of fetal ECG waveforms over time, as is required by Claim 22. As above, Applicants contest the Examiner's assertion (Examiner's Action of January 25, 2010, page 3, lines 9-13) that Oriol '776 determines these differences in shape with at least one of the steps of matching the ECG complex waveforms to a plurality of stored templates, detecting a change of phase of one waveform relative to an adjacent waveform, and detecting changes in the amount of energy in the fetal ECG complex by integration.

Paragraph [0131] does not teach matching the waveforms to a template. As stated above, paragraph [0131] references a "specific pattern," but this refers only to the individual ECG pattern associated with a particular patient, not a pattern that has been stored as a template. Therefore, paragraph [0131] does not teach matching the waveform to a template.

Nor does paragraph [0131] of Oriol '776 disclose detecting a change in phase of one ECG complex relative to an adjacent ECG complex or detecting changes in the amount of positive and/or negative energy in the fetal ECG waveform by integration. Paragraph [0131] discusses that the literature has established what variables should be monitored as well as providing plots of these important variables (lines 13-15). However, at no place in paragraph [0131], or in the entire Oriol '776 specification, can the Applicants find any teaching of matching the waveforms to a plurality of stored templates, detecting changes of the phase of one waveform relative to an adjacent waveform, or detecting changes in the amount of energy in the fetal ECG complex by integration. Nagel neither discloses nor suggests these steps, either. The failure of either reference to disclose or suggest these steps shows that Claims 22-29, 37, and 38 are patentable over Oriol '776 and Nagel.

Claims 4 and 24

Claims 4 and 24 are patentable at least for their dependence on Claims 1 and 22, respectively. Neither Oriol '776 nor Nagel teaches a waveform preprocessor that includes a discriminator for distinguishing between the maternal and fetal ECG complex waveforms. As described by the Applicants' specification at page 14, lines 20-23, the preprocessor distinguishes between the fetal ECG waveform and the maternal ECG waveform using predetermined, stored templates.

Conversely, Nagel *locates* a complex with the Cross Correlation Function (CCF) in the equation at column 5, line 64 of Nagel, but it does not *identify* the complex. Nagel locates a complex using an average of the Fetal ECG complex M(t), which is derived from the signal itself. Stated another way, Nagel locates a complex only when the raw data matches the data itself. This has the inherent limitation of being susceptible to locating false peaks because the

system frequently matches signal noise instead of the fetal or maternal heartbeats. This problem is not present in the Applicants' method or apparatus because the waveform templates have been preprogrammed. It is this feature that allows the Applicants to *identify*, rather than merely *locate*, the fetal and maternal ECG waveforms.

Claims 7 and 27

Claims 7 and 27 are patentable at least for their dependence on Claims 1 and 22, respectively. Further, neither reference teaches that a template stored within the waveform processor corresponds to a specific fetal spatial presentation and/or position. Nagel merely concerns itself with detecting, storing, and processing the QRS complexes of the fetal ECG waveform, column 3, lines 45-50.

Nagel does not teach, however, the critical concept presented by the Applicants, i.e., the shape and form (waveform) of the fetal ECG data can be associated with a *particular spatial presentation or position* of the fetus. Applicants' apparatus does much more than merely store and display received QRS data. As such, Claim 7 and 27 are patentable in view of Oriol '776 and Nagel for this additional reason.

Claims 9 and 28

Claims 9 and 28 are patentable at least for their dependence on Claims 1 and 22. Further, neither Oriol '776 nor Nagel teaches that the event logger records occasions on which the determined template changes. In paragraphs [0081] and [0094], Oriol '776 mentions briefly that a fetal movement analyzer can be used to detect the occurrence of movement but this falls well short of teaching the claimed step of recording the number of times that a recognized template changes. Instead, Nagel only teaches detection of movements of the fetal heart as they relate to the QRS complexes, column 3, lines 36-41.

The Applicants' recordation of the movements represents a substantial advance over the storage of ECG data in Nagel. Not only does the claimed system determine the position of the fetus from the shape of the fetal ECG waveform, it determines the *number* of changes in position by determining the number of times that the matching template changes. This capability is far beyond the teachings of Nagel and Oriol '776 because the Applicants' apparatus records not only the *occurrence* of movement, but the frequency and *type* of movement.

C. Rejection of Claims 12-14 and 31-33 under 35 U.S.C. §103(a) over Oriol '776 in view of Nagel and Beach

Claims 12-14 and 31-33 are patentable at least for their dependence on Claims 1 and 22. Claims 12 and 31 are apparatus and method claims, respectively, which recite structure or a step for detecting changes. The Examiner states that it would have been obvious to one of skill in the art to modify the ultrasound phase detector of Beach for use with the ECG apparatus of Oriol '776 and Nagel. The combination of an ultrasound phase detector with an ECG apparatus is unreasonable because the two technologies are very different from one another. The ultrasound process of Beach does not require preprocessing of a signal to discriminate between fetal and maternal waveforms. Further, the ultrasound process is an active process that projects bursts of sound waves into the body and measures the reflections to generate a two dimensional image.

Conversely, ECGs involve passive monitoring of the natural electrical signals generated by the body or, in this case, the fetus and the mother. In the absence of a template, an ECG cannot be used to create an image but only creates a trace showing the electrical activity of the maternal and fetal hearts. Since the two technologies use very different signals, it would not have been obvious to one of skill in the art combine the ultrasound phase detection of Beach with the ECG apparatus of Oriol '776 and Nagel.

D. Rejection of Claims 15-17, 20, 34-36, and 39 under 35 U.S.C. §103(a) over Oriol '776 in view of Nagel and Oriol '993

Claims 15, 20, 34, and 39

With regard to Claims 15 and 34, the Examiner cites Oriol '993 for the proposition that it is known to use a time plot of the base line signal showing decelerations associated with the loss of variability (Examiner's Action of January 25, 2010, page 5, lines 16-19). While Oriol '993 describes using the plots of the heart rate signal and the uterine contraction signal to analyze decelerations, it stops well short of teaching the detection of changes in the relative proportions of energy *above* and *below* a baseline reference.

As used by the Applicants, the changes in the positive and/or negative energy of the fetal waveform can be used to determine when the shape of the waveform has changed, thereby indicating when the fetus has changed to a different spatial presentation or position. For example, this technique can be used to determine if the pattern changes from type A to type B of Figure 5. While detection of the change can be done by a number of different methods, Applicants teach that the detection can be done by integration, or summing the area under the curve. Oriol '993 does not teach using the technique of integration. Instead, Oriol '993 looks at the plot only to determine a deceleration pattern of the fetal heart beat. The Applicants, however, use the information to look beyond the heartbeat, using the waveform to detect a change in presentation or position of the fetus itself. No combination of prior art references does this.

Claims 16 and 35

Claims 16 and 35 are patentable at least for their dependency on Claims 1 and 15 and Claims 22 and 34, respectively. Further, none of the references teaches or makes obvious using the isoelectric line as the baseline reference.

Claims 17 and 36

Claims 17 and 36 are patentable at least for their dependency on Claims 1 and 15 and Claims 22 and 34, respectively. Further, none of the references teaches or makes obvious the step of using the previous or average waveform as the reference.

In summary, the crucial distinction of the Applicants' invention over the prior art is that, unlike the prior art, it goes beyond simple analysis of the ECG signals to determine the health of the fetus. The prior art provides only a limited view of the overall picture. The Applicants have determined how to extrapolate additional valuable data from the ECG signals to provide more of the overall picture by using the ECG signals to determine (through comparison with templates, phase detection, or integration) the *spatial position and presentation* of the fetus. Applicants also record the *number of changes* in position and/or presentation, providing a further indication of the well-being of the fetus. These features simply are not disclosed or made obvious by the prior art.

Applicants have demonstrated that the Examiner did not have substantial evidence to support her rejections in view of the prior art. Applicants, therefore, respectfully request the Board to reverse the Examiner's rejections and to order that a Notice of Allowance be issued on this patent application.

VIII. CLAIMS APPENDIX

1. Apparatus for monitoring fetal behaviour comprising:

   (i) an input for receiving ECG data from a set of electrodes adapted to be attached to a maternal abdomen;

   (ii) a waveform pre-processor for identifying a succession of fetal ECG complex waveforms within the received data;

   (iii) a waveform processor for determining differences in the shapes of a succession of fetal ECG complex waveforms over time, the waveform processor including at least one of a comparator for matching the ECG complex waveforms to a plurality of stored templates, a phase detector for detecting a change of phase of one ECG complex relative to an adjacent ECG complex, and an integrator for detecting changes in the amount of positive and/or negative energy in the fetal ECG Complex waveforms; and

   (iv) an event logger determining from the determined differences a number of fetal body movements during the period of time.

2. The apparatus of claim 1 further including a plurality of electrodes for positioning at different locations on the maternal abdomen.

3. The apparatus of claim 2 in which the number of electrodes is two.

4. The apparatus of claim 1 in which the waveform pre-processor includes a discriminator for discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform.

5. The apparatus of claim 4 in which the waveform pre-processor includes means for subtracting the maternal ECG complexes from the received waveform.

6. The apparatus of claim 1 in which the waveform pre-processor comprises means for identifying a QRS complex in the fetal ECG data.

7. The apparatus of claim 1 in which the waveform processor comprises:

(i) a memory storing a plurality of fetal ECG complex templates each corresponding to a specific fetal spatial presentation and/or position;

(ii) a comparator for comparing each of the identified fetal ECG waveforms with a set of predetermined ones of the fetal ECG complex templates and determining at least one template from said set of templates that best matches each identified fetal ECG waveform.

8. The apparatus of claim 7 in which the memory stores a plurality of fetal ECG complex templates each corresponding to a specific fetal spatial presentation and/or position relative to a specific one of a plurality of different electrode configurations.

9. The apparatus of claim 7 in which the event logger records occasions on which the determined template changes.

10. The apparatus of claim 7 further including means for selecting the set of predetermined fetal ECG templates according to a preselected one of a plurality of configurations of ECG electrodes positioned on the maternal abdomen.

11. The apparatus of claim 7 in which the set of predetermined fetal ECG templates includes templates corresponding to at least cephalic presentation, breech presentation, shoulder dorsoanterior presentation and shoulder dorsoposterior presentation.

12. The apparatus of claim 1 in which the waveform processor comprises means for detecting phase changes between successive fetal ECG complex waveforms.

13. The apparatus of claim 12 in which the waveform processor comprises means for detecting phase changes of one or more predetermined magnitudes between successive fetal ECG complex waveforms.

14. The apparatus of claim 12 in which the event logger records occasions on which a phase change occurs.

15. The apparatus of claim 1 in which the waveform processor is adapted to determine differences in fetal complex waveforms by detecting change in the relative proportions of energy of a fetal ECG complex waveform above and below a baseline reference.

16. The apparatus of claim 15 in which the baseline reference is the isoelectric line of a fetal ECG complex.

17. The apparatus of claim 15 in which the reference is derived from a previous or average fetal ECG complex waveform.

18. The apparatus of claim 1 further including a display for displaying a count of the number of fetal body movements detected.

19. The apparatus of claim 1 wherein the waveform processor further includes a fetal heart rate monitor.

20. The apparatus of claim 1 further including an alarm for indicating if the number of fetal body movements during a period of time falls below a predetermined threshold.

21. The apparatus of claim 1 further including a memory for storing fetal body movement event data and an electronic interface for downloading said event data to a remote device.

22. A method for monitoring fetal behaviour comprising:

(i) obtaining fetal ECG data over a period of time;

(ii) identifying a succession of fetal ECG complex waveforms within the data;

(iii) determining differences in the shapes of a succession of fetal ECG complex waveforms over time, said step of determining differences including at least one of the steps of matching the ECG complex waveforms to a plurality of stored templates, detecting a change of phase of one ECG complex relative to an adjacent ECG complex, and detecting changes in the amount of positive and/or negative energy in the fetal ECG complex waveforms by integration; and

(iv) determining from the determined differences a number of fetal body movements during the period of time.

23. The method of claim 22 in which step (i) comprises obtaining fetal ECG data from a plurality of electrodes positioned at different locations on the maternal abdomen.

24. The method of claim 23 in which step (ii) includes the step of discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform.

25. The method of claim 24 in which step (ii) includes subtracting the maternal ECG complexes from the received waveform.

26. The method of claim 22 in which step (ii) comprises identifying a QRS complex in the fetal ECG data.

27. The method of claim 22 in which step (iii) includes:

(i) comparing each of the identified fetal ECG waveforms with a set of predetermined fetal ECG complex templates; and

(ii) determining at least one template from said set of templates that best matches each identified fetal ECG waveform.

28. The method of claim 27 in which step (iv) comprises determining the number of successive occasions on which the determined template changes during the period of time.

29. The method of claim 27 in which the set of predetermined fetal ECG templates is selected according to a preselected one of a plurality of configurations of ECG electrodes positioned on the maternal abdomen.

30. The method of claim 27 in which the set of predetermined fetal ECG templates includes templates corresponding to at least cephalic presentation, breech presentation, shoulder dorsoanterior presentation and shoulder dorsoposterior presentation.

31. The method of claim 27 in which step (iii) comprises detecting phase changes between successive fetal ECG complex waveforms.

32. The method of claim 22 in which step (iii) comprises detecting phase changes of one or more predetermined magnitudes between successive fetal ECG complex waveforms.

33. The method of claim 31 in which step (iv) comprises determining the number of successive occasions on which a phase change occurs during the period of time.

34. The method of claim 22 in which the differences determined in step (iii) comprise change in the relative proportions of energy of a fetal ECG complex waveform above and below a baseline reference.

35. The method of claim 34 in which the baseline is the isoelectric line of a fetal ECG complex.

36. The method of claim 34 in which the reference is derived from a previous or average fetal ECG complex waveform.

37. The method of claim 22 further including the step of displaying or logging a cumulative count of the number of fetal body movements within the period of time.

38. The method of claim 22 further including the step of monitoring fetal heart rate.

39. The method of claim 22 further including the step of indicating an alarm condition if the number of fetal body movements during the period of time falls below a predetermined threshold.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

The required fees as set forth in 37 C.F.R. §41.20(b)(2) are being charged to Deposit Account No. 503982 of Momkus McCluskey, LLC. The owner of this Application is not a small entity. Applicant believes that no other fee is due, but the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to the same deposit account

Respectfully submitted,

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